

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**THE CITY OF HUNTINGTON,
Plaintiff,**

v.

CIVIL ACTION NO. 3:17-01362

**AMERISOURCEBERGEN DRUG
CORPORATION, et al.,
Defendants.**

**CABELL COUNTY COMMISSION,
Plaintiff,**

v.

***Consolidated case:*
CIVIL ACTION NO. 3:17-01665**

**AMERISOURCEBERGEN DRUG
CORPORATION, et al.,
Defendants.**

**PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR
PARTIAL SUMMARY JUDGMENT HOLDING THAT CARDINAL HEALTH
DID NOT COMPLY WITH ITS DUTIES UNDER THE CONTROLLED
SUBSTANCES ACT**

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INTRODUCTION

Cardinal Health does not dispute that it shipped orders of opioids that it deemed suspicious without conducting due diligence prior to shipment. Prior to 2008, Cardinal Health generated monthly Ingredient Limit Reports ("ILRs") to identify suspicious orders that exceeded threshold amounts. While it reported the orders that exceeded its threshold to the Drug Enforcement Agency ("DEA") as suspicious, it did so only after it shipped the orders. This was a clear violation of its duty to refrain from shipping suspicious order without clearing the suspicion first. Cardinal's excuse — that it had an effective suspicious order monitoring system in place given DEA's evolving guidance at that time — is disingenuous and wrong as a matter of law.

As a matter of law, Cardinal had the duty to not ship orders deemed suspicious without conducting due diligence. The undisputed facts establish that from 2006 through 2008, Cardinal failed to stop orders it deemed suspicious because of their unusual size,¹ and it did so without conducting any due diligence. In total, the undisputed data from the ILRs reflects that during this period, 239 orders of opioids exceeded the threshold limit comprising 248,044 opioid pills over this time period.²

This Court should grant partial summary judgment on this clear violation of the Controlled Substances Act ("CSA").

¹ See 21 C.F.R. § 1301.74(b).

² See Opening Brief, Ex. 4A, Summary of CAH Orders Shipped to T2 Pharmacies Where Order Was Over Distribution Center Ingredient Limit.

ARGUMENT

I. The CSA Required Cardinal to Identify and Report Suspicious Orders and to Halt Shipment of Such Orders Pending Investigation.

Cardinal denies that it had the legal duty to decline to ship an order identified as suspicious unless and until, through due diligence, it was able to determine that the order is not likely to be diverted into illegal channels (the “no-shipping duty”). As a matter of law, Cardinal was under a duty to halt shipment of suspicious orders of controlled substances pending investigation.³ Cardinal’s arguments in this regard echo Defendants’ opposition to the Plaintiffs’ CSA Duty Motion,⁴ and, in response, Plaintiffs incorporate their contemporaneously filed reply briefing on that motion.⁵

Cardinal offers one new argument not previously addressed. Cardinal argues that the DEA’s interpretation through informal communications here is entitled to less deference because it conflicts with DEA’s prior interpretation. Cardinal is wrong.

Cardinal identifies no DEA regulation or adjudication authorizing a registrant to ship, and continue to ship, orders that it acknowledged raised suspicions of diversion to non-medical use. An agency refusal to enforce is not a statutory interpretation as it “involves a complicated balancing of a number of factors which

³ See Memo in Support of CSA Duty Motion (“CSA Duty Memo”), Doc. 1018-0 at pp. 5-15.

⁴ See Doc. 1079.

⁵ Reply Memo in Support of CSA Duty Motion (“CSA Duty Reply”), Doc. 1145 at pp. 4-18.

are peculiarly within [the agency's] expertise.”⁶ In any event, even under Cardinal's argument, less deference does not mean no deference.

Moreover, Cardinal's legal authority supports the DEA's actions here. In *Shalala v. Guernsey Mem'l Hosp.*, the Supreme Court found that agency informal guidance letters were permissible unless the agency “adopted a new position *inconsistent* with any of the [agency's] existing regulations.”⁷ The no-ship duty is not inconsistent with any regulation. Indeed, in *Shalala* the Court explicitly recognized that there is no “basis for suggesting that [an agency] has a statutory duty to promulgate regulations that, either by default rule or by specification, address every conceivable question.”⁸ And, as the Court noted, the Administrative Procedures Act “does not require that all the specific applications of a rule evolve by further, more precise rules rather than by adjudication.”⁹

For these reasons and the reasons noted in the CSA Duty Reply, this Court should conclude that the no-shipping duty exists as a matter of law.

⁶ *Heckler v. Chaney*, 470 U.S. 821, 831, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985).

⁷ 514 U.S. 87, 99–100, 115 S. Ct. 1232, 1239, 131 L. Ed. 2d 106 (1995) (emphasis added).

⁸ 514 U.S. at 96, 115 S. Ct. at 1237. Similarly, Cardinal's citation of *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415, 204 L. Ed. 2d 841 (2019), Opp. at 20, does not compel rejection of the no-ship requirement. The cited passage was in the context of a regulation with only “one reasonable construction.” *Id.* Here, the DEA's construction addressed any issue that was not explicitly provided for under the statute or the regulation – whether the statutory duty to maintain effective controls against diversion required Cardinal to refrain from shipping orders it deemed suspicious under the regulation.

⁹ *Id.*

II. Cardinal's Evidence of Prior DEA Inspections and/or Purported Approval of its SOM Programs cannot Defeat Summary Judgment.

Cardinal relies on communications from the DEA prior to 2007 supposedly approving its suspicious order monitoring procedures. This argument neither defeats the existence of the no-shipping duty nor excuses Cardinal's failure to comply with it.

First, for the reasons noted in Plaintiffs' CSA Duty Reply, the evidence of prior DEA inspections and/or the purported approval of their suspicious order monitoring systems does not create a triable issue of fact.¹⁰ The no-shipping duty presents a question of law, and as Judge Polster found, any evidence that the no-shipping was not always the law is irrelevant.¹¹

Similarly, notwithstanding Cardinal's argument to the contrary, Judge Polster did not deny summary judgment on the Plaintiffs' Track 1 summary judgment motion because this testimony created a factual issue over whether a duty existed. As noted in the CSA Duty Reply, in his December 26, 2019 Order, Judge Polster expressly rejected that characterization of his prior SOM's order: "In fact, the Court held that material issues of fact existed as to whether defendants had violated or not substantially complied with their duties under the CSA — not whether the duties themselves had always existed or changed over time."¹²

Cardinal alleges that Plaintiffs improperly mischaracterize their suspicious order monitoring system as containing only one component, the monthly reporting of

¹⁰ CSA Duty Reply, Doc. 1145 at 14-18.

¹¹ *Id.* at p. 14.

¹² *Id.* at 15 (quoting MDL Doc. 3052 at p. 25, n.49).

ILRs. According to Cardinal, it had a two-part system in place that consisted of i) the submission of ILRs and ii) the monitoring and reporting of single suspicious orders based on cage and vault personnel's first-hand knowledge of the customers and their purchasing patterns.¹³ On this record, however, there is no factual dispute that this supposed second part did not constitute compliance with the no-shipping duty.

The second part of Cardinal's purported system was hardly robust.¹⁴ Cardinal has failed to identify a single order shipped to a Cabell or Huntington pharmacy during this time period that was reported as suspicious under the second component of its system. Nor has it shown that any of these orders were stopped by the cage and vault personnel. More importantly, Cardinal does not dispute that the suspicious orders identified in the ILR reports were all shipped, and it does not contend that *any* diligence was performed on these orders prior to shipment. Thus, while the two-component system may have existed in theory, the existence of the second component is irrelevant to the question of whether the orders in excess of Cardinal's ingredient limit identified in the instant motion were in violation of the CSA because they were shipped without conducting due diligence.

¹³ See Opp. at 4-5.

¹⁴ See Opp. at p. 4 ("on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, *if possible*, before the order is shipped " (emphasis added) (quoting Opp. Exhibit 2)).

Finally, Cardinal contends that it was not aware of the requirement to stop shipment of suspicious order until late 2007.¹⁵ Cardinal's knowledge (or lack of knowledge) of the existence of the no-shipping duty is irrelevant to the question of law about whether the no-shipping duty existed because the duty is a question of law. The testimony of Cardinal's 30(b)(6) designee, Jennifer Norris, however, establishes that Cardinal was aware of a "genera[l]" no-shipping requirement in 2006 before the vast majority of the orders subject to this motion were shipped.¹⁶

Here, on this record, Plaintiffs have focused on the 239 orders Cardinal admits that it determined were suspicious yet shipped in violation of the no-ship duty. The analysis is simple. The duty not to ship without conducting due diligence existed well before 2007 as a matter of law. Cardinal does not dispute that it shipped 239 invoiced orders which contained 3,631,990 milligrams of opioids comprising 248,044 dosage units without conducting due diligence.¹⁷ On this record, summary judgment is appropriate.

¹⁵ Opp. at 7-8.

¹⁶ Opening Brief at Exhibit 12. ("Q: . . . So do you believe that within the 2006 registrant letter, there is a statement imposing a shipping requirement? A: Generally speaking, yes."); *id.* at 173:23-174:1-4 ("Q: Is it Cardinal's position or understanding that the initial Rannazzisi letter in 2006 informed them of a shipping requirement as we've described it? A: Yes. That was the first communication Cardinal received regarding this sea of change of adding a shipping requirement to the obligation."), *id.* at 135:10-16. Indeed, Ms. Norris testified that she was aware that Cardinal's practices may constitute "engaging in activities that do not comply with the statute, regulations, and DEA's guidance." *id.* at 172:9-16.

¹⁷ Opening Memo, Doc. 1016 at 10.

CONCLUSION

For the foregoing reasons, the Court should grant Plaintiffs' request for summary adjudication and should find, as a matter of law, that Cardinal's shipping of suspicious orders as identified in its ILRs violated its duties under the CSA to maintain effective controls against diversion.

Dated: October 30, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on October 30, 2020, a copy of the foregoing **PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT HOLDING THAT CARDINAL HEALTH DID NOT COMPLY WITH ITS DUTIES UNDER THE CONTROLLED SUBSTANCES ACT** has been filed electronically using the Court's CM/ECF system and will be served *via* the Court's CM/ECF filing system, which will send notification of such filing to the attorneys of record at their e-mail addresses on file with the Court.

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